

IACUC should probably not approve that possibility and should certainly not do so without USDA review.

1. Institute of Laboratory Animal Resources. *Guide for the Care and Use of Laboratory Animals* (National Institutes of Health, Bethesda, MD, 1978).
2. United States Department of Agriculture, Animal and Plant Health Inspection Service. 9 CFR Part 3 Animal Welfare; Standards; Final rule. *Federal Register* 56, 6426–6505 (1991).
3. United States Department of Agriculture. Policy #14: Major Survival Surgery Dealers Selling Surgically-Altered Animals to Research. in *Animal Care Policy Manual* (USDA, Beltsville, MD, 2011).
4. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).

Carbone is Associate Director of the Laboratory Animal Resource Center of the University of California San Francisco, San Francisco, CA.

RESPONSE

Consider a combined protocol

Ronald P. Wilson, VMD, MS, DACLAM,
Jennifer L. Booth, DVM &
Jenelle M. Tretter, DVM

The Great Eastern University IACUC cannot approve Benoit's protocol amendment. Because rabbits are covered by the USDA, Great Eastern University must abide by the Animal Welfare Act. The Animal Welfare Regulations (AWRs; § 2.31,d,1,x)¹ and APHIS Policy #14 (ref. 2) state that "no animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, required as a routine veterinary procedure or to protect the health or well-being of the animal, or in other special circumstances as determined by the Administrator of APHIS." The *Guide for the Care and Use of Laboratory Animals* (the *Guide*) suggests that reasons for major multiple survival surgeries may include procedures that are related components of a single research project or protocol, procedures that will conserve scarce animal resources or procedures conducted for clinical reasons³. The *Guide* further states that "the application of such a practice on a single animal used

A word from USDA

In response to the questions posed in this scenario, the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA/APHIS/AC) offers the following clarification and guidance:

The Animal Welfare Act (AWA; §2143(a)(3)(D) and the Animal Welfare Act Regulations (AWARs; §2.31(d)(1) (x)) state that no animal is to be used in more than one major operative procedure from which it is allowed to recover except in cases of scientific necessity or approved as a Special Circumstance¹. A major operative procedure is defined in §1.1 of the AWARs as any surgical intervention that penetrates and exposes a body cavity or any procedure that produces permanent impairment of physical or physiologic function¹. In this scenario, there are two major operative procedures of concern: an ovariectomy that penetrates a body cavity, and a fracture induction that the IACUC has already determined to be a major operative procedure.

Under Policy 14, a second major survival operative procedure must not be performed on an animal in a separate animal study activity without the proper approvals². In order to combine the two protocols in this scenario, the investigators should write a new protocol containing clear objectives and appropriate justifications for the two major operative procedures that must be approved by the IACUC. If the new protocol is approved by the IACUC, APHIS approval is not required.

In the event that the investigator who performs fracture induction decides to amend the protocol to add the ovariectomized rabbits, two things must occur before the proposed activity is to begin. First, the IACUC must approve the amendment, and second, a written request must be submitted by the Institutional Official to the APHIS Animal Care Regional Office for approval as a Special Circumstance².

The request to APHIS should include the following ten parts: (i) an outline of the research proposal for which the procedure is requested; (ii) a means by which to uniquely identify the research proposal; (iii) the species and the approximate number of animals involved in the exemption request; (iv) a method of permanently identifying the individual animals involved; (v) the time frame for the proposed exempt procedure; (vi) the number of major operative procedures to be performed on a given animal, the frequency of such procedures and the period of time between each major operative procedure; (vii) measures to be taken to ensure that pain and distress are minimized; (viii) a complete scientific justification for the exemption (cost is not an acceptable justification); (ix) an assurance that all other stipulated requirements of the AWA and regulations will be met in consideration of this exemption; and (x) an assurance that the facility's IACUC has approved the exemption.

The APHIS response may be to approve the request as written, to request further information, to impose additional limitations or to deny the request. If the request is approved, an annual IACUC evaluation of the exemption is required, which consists of an IACUC assessment of the animals and the effectiveness and soundness of the methods and procedures used. This information is to be included in the semiannual report to the Institutional Official and the Annual Report (APHIS Form 7023) submitted to the Regional Office. A request to renew or continue the exemption must be submitted to APHIS before the approval period expires².

1. Code of Federal Regulations, Title 9, Ch. 1
2. United States Department of Agriculture. Policy #14: Major Survival Surgery Dealers Selling Surgically-Altered Animals to Research. in *Animal Care Policy Manual* (USDA, Beltsville, MD, 2011).

Chester Gipson, DVM

Deputy Administrator
USDA, APHIS, AC

in separate protocols is discouraged"³, and APHIS Policy #14 states that "a 2nd major survival operative procedure must not be performed on an animal in a separate

animal study activity"². The first surgical procedure, ovariectomy, penetrates a body cavity, and the second surgical procedure, induction of long bone fracture, results in